BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A non-aqueous tape preparation comprising ~~an~~ a nonaqueous adhesive mass ~~comprising~~ consisting essentially of 1-30 parts by weight of a local anesthetic in a base form in 100 parts by weight of ~~a~~ the nonaqueous adhesive mass base, ~~comprising~~ 5-50% by weight of a styrene-isoprene-styrene block copolymer, 1-60% by weight of an alicyclic saturated hydrocarbon resin, 5-60% by weight of liquid paraffin and 1-30% by weight of butyl rubber,

wherein the adhesive mass is supported on a backing, and

wherein the local anesthetic is at least one selected from the group consisting of lidocaine, procaine, oxyprocaine, dibucaine, bupivacaine, mepivacaine, and propitocaine.

Claim 2 (Previously Presented): A tape preparation as claimed in Claim 1, wherein the effect of the local anesthetic lasts for 24 to 72 hours.

Claim 3 (Previously Presented): A tape preparation as claimed in Claim 1 which causes stratum corneum abrasion only to a slight extent even when applied continuously for a long period of time.

Claim 4 (Previously Presented): A tape preparation as claimed in Claim 1 which is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

Claim 5 (Previously Presented): A tape preparation as claimed in Claim 1 which is excellent in duration of effect on alleviating pains on the occasion of high frequency therapy

or laser therapy, pains upon treatment of liver spots or dark red birthmarks, pains upon biopsy, pains on the occasion of skin grafting for the treatment of thermal burns, or pains on the occasion of treatment of molluscum contagiosum.

Claim 6 (Canceled).

Claim 7 (Previously Presented) A tape preparation as claimed in Claim 1, wherein the local anesthetic is lidocaine.

Claim 8 (Canceled).

Claim 9 (Canceled).

Claim 10 (Previously Presented): A tape preparation as claimed in Claim 1 which causes stratum corneum abrasion only to a slight extent even when applied continuously for a long period of time, and is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

Claim 11 (Currently Amended): The preparation of Claim 1, wherein the alicyclic saturated hydrocarbon is present in an amount of from 10-50% by weight.

Claim 12 (Currently Amended): The preparation of Claim 1, wherein the styrene-isoprene-styrene block copolymer is present in an amount of from 10-40% by weight.

Claim 13 (Currently Amended): The preparation of Claim 1, wherein the liquid paraffin is present in an amount of 10-40% by weight.

Claim 14 (Currently Amended): The preparation of Claim 1, wherein the butyl rubber is present in an amount of from 5-15% by weight.

Claim 15 (Previously Presented): The preparation of Claim 1, wherein the butyl rubber has a molecular weight of not less than 400,000.

Claim 16 (Currently Amended): The preparation of Claim 1, wherein the local anesthetic in a base form is present in an amount of from 5-20% by weight.

Claim 17 (Currently Amended): The composition of Claim 1 further ~~comprising~~ consisting essentially of a filler, an antioxidant or a mixture thereof.

Claim 18 (Previously Presented): The preparation of Claim 1, wherein the backing has a thickness of from 50-500 μm.

Claim 19 (Currently Amended): The preparation of Claim 1, wherein the adhesive mass ~~comprises~~ consists essentially of five parts of lidocaine, 22 parts of the styrene-isoprene-styrene block copolymer, five parts of the butyl rubber, 33 parts of the alicyclic saturated hydrocarbon resin, 30 parts of the liquid paraffin, 5 parts of titanium oxide, and 0.1 parts of an antioxidant ~~part antioxidants~~.

BASIS FOR THE AMENDMENT

Claims 1-5, 7 and 10-19 are active in the present application. Claims 6 and 8-9 have been canceled. Claim 1 has been amended to limit the tape preparation to non-aqueous tape preparations. Support for the amendment is found on page 9, lines 15-18. Claim 1 has been further amended to include the transitional phrase "consisting essentially of". Support for the amendment is found in the paragraph bridging pages 9 and 10; the Examples where adhesive masses containing only those components recited in present Claim 1, a filler, an antioxidant (see dependent Claim 17) and no water are disclosed (page 10, lines 6-15); and the disclosure in the specification noting that the presence of water may negatively affect the ability of the claimed composition to deliver a local anesthetic to the skin (pages 5-6). Claims 17 and 19 have been amended in accordance with the amendment to Claim 1. No new matter is believed to have been added by this amendment.

REQUEST FOR RECONSIDERATION

Applicants thank Examiner Gollamudi for the helpful and courteous discussion of October 21, 2003. During the discussion, Applicants U.S. representative presented arguments that the butyl rubber of the claimed tape preparation preferably has a molecular weight of 400,000 or greater and such butyl rubbers may not be disclosed in the prior art cited by the Office.

Applicants have claimed a non-aqueous tape preparation that allows sustained percutaneous delivery of a local anesthetic (page 1, lines 6-9). The claimed tape preparation allows the local anesthetic to be absorbed through the skin in a stable manner over a long period of time (page 1, lines 11-13). Applicants have disclosed that the presence of water in such tape preparations is not advantageous to the stable and long term delivery of the local anesthetic agent (page 5, line 7 – page 6, line 2). Since a local anesthetic such as lidocaine is only slightly soluble in water or a water retaining agent, the presence of water in a tape preparation may result in crystals of the local anesthetic precipitating from the tape preparation (page 5, lines 16-20). Although salts of local anesthetics may be used in place of the base form of the local anesthetic it is difficult to achieve percutaneous delivery of a local anesthetic when it is in a salt form (page 5, lines 20-24).

Applicants' claimed tape preparation provides stable percutaneous delivery of a local anesthetic over a long period of time while concurrently providing good adherence to skin. The claimed tape preparation may be removed painlessly from the skin and does not cause an excessive abrasion of the stratum corneum (e.g., dead and dying cells on the outermost layer of the epidermis which may be filled with keratin) upon removal (page 7, lines 1-2).

Claim 1 has been amended herein to include the transitional phrase "consisting essentially of". The transitional phrase "consisting essentially of" is used to describe compositions which contain at least the components explicitly recited in the claim and may

further contain additional components so long as the additional components do not materially affect the basic and novel characteristics of the claimed invention. As stated in In re Janakirama-Rao, 137 USPQ 893 (CCPA 1963), "[t]he term 'essentially' opens the claims to the inclusion of ingredients which would *not* materially affect the *basic and novel* characteristics of Applicants' composition..." (emphasis in the original; see also MPEP § 2111.03-Transitional Phrases)

The basic and novel characteristics of the presently claimed tape preparation include the ability to percutaneously deliver a local anesthetic in a stable manner over a long period of time and the ability to adhere to the skin (page 6, line 25). As disclosed in the present specification, the presence of water can negatively affect the delivery of a local anesthetic in its base form by causing the local anesthetic to precipitate and/or crystallize.

The Office rejected the claims in view the combination of JP 10-147521 or JP 07-126157 with Kubo (U.S. 5,827,528). The Office relied upon the Kubo reference as a teaching that butyl rubber may be present in prior art compositions in the amount specified in present Claim 1.

Applicants traverse the rejection on the grounds that the compositions of Kubo are required to contain a water absorbing agent that would materially affect the ability of a tape preparation to adhere to the skin and to percutaneously deliver a base-form local anesthetic in a stable manner over a long period. Applicants submit that a reasonable expectation of success is lacking in the combination of prior art relied upon by the Office to prepare the presently claimed adhesive mass which excludes water and water absorbing components. The rejection is therefore unsustainable and should be withdrawn.

Kubo discloses that the prior art medical adhesives have improved water absorbent characteristics (Abstract). Kubo further discloses in the Background of the Invention section of the patent (column 1, line 55 through column 2, line 49) that the inclusion of a water

absorbing agent is known in the art. Water absorption is an important characteristic of the prior art compositions. The prior art absorbent allows the prior art compositions to absorb sweat and wound exudates (column 1, lines 36-42). The water absorbing component of Kubo is an essential element of the prior art compositions (see independent Claims 1 and 6 of Kubo).[1]

Applicants submit concurrently herewith a Declaration under 37 C.F.R. § 1.132. In the Declaration the invention composition is compared with a number of similar compositions which additionally contain water or a water absorbing component. The compositional formulations of the invention preparation and the comparative preparations are provided in Table 1 of the Declaration. At least two of the comparative preparations (e.g., comparative preparation 3 which contains Karaya gum as the water absorbing agent and comparative preparation 4 which contains water) are unable to function in the claimed adhesive preparation because the composition either forms spots on the surface of the adhesive mass or separates from the adhesive mass thereby failing to provide a homogeneous adhesive mass.

Comparative preparations 1 and 2 contain carboxymethyl cellulose or gelatin as the water absorbing component respectively. The Declaration demonstrates that the comparative preparations are unable to provide the adhesion to skin of the invention preparation. It is readily evident from Table 2 of the Declaration that the comparative preparations, when used on a backing or support and adhered to the skin, have a substantially greater tendency to fall from the skin when the adhesive preparation is placed on skin and immersed in water. The ability of the claimed adhesive preparation to adhere to the skin is one of the claimed compositions basic and novel characteristics (see page 6, line 25). Applicants' Declaration

[1] The water absorbing agent of Kubo is nowhere disclosed to act as a dessicant in order to provide a water free environment for the prior art medical adhesive.

demonstrates that a non-aqueous adhesive preparation that excludes water or water absorbing components is different from the compositions of the prior art references cited against the present claims as evidenced by the claimed composition's ability to adhere to the skin even under conditions in which the claimed tape preparation is immersed in water.

One of the materials of the Kubo composition is described as an elastomer having a low compatibility (such as isobutylene). This material is disclosed to have an important interaction with the water absorbing component:

> Therefore, upon contact with water or exudates, the water absorbent component contained in a large amount in the elastomer having a low compatibility with the thermoplastic elastomer exhibits a high water absorption characteristic. Further, the water or the exudates absorb diffusing the adjacent water absorbent component, thus securing the amount of water absorbed. In this case the thermoplastic elastomer serves as a skeleton and since the skeleton component and the low compatibility elastomer have an affinity, they are not pushed out, so that only the water absorbent component which has absorbed the water is lowered in its affinity with the elastomer and enhanced in its flowability and thus pushed out.

It appears that the water absorbing component of Kubo may function to compatibilize water with the prior art elastomer and water is therefore an essential element in the prior art elastomeric material. From the disclosure cited above it appears that the prior art elastomer provides its benefits at least in part because of the presence of the water absorbing component. Applicants submit that one of ordinary skill in the art may not be motivated to include the Kubo elastomer in an adhesive composition which is formulated to exclude water absorbing components as evidenced by Kubo's disclosure that the interaction of the elastomer with the water absorbing component is an important feature of the prior art's performance attributes.

Applicants submit that those of ordinary skill in the art would not have a reasonable expectation of successfully preparing a composition which is able to adhere to the skin and percutaneously deliver a local anesthetic in a stable manner over a long period of time by

including water (e.g., a water absorbing agent) in a composition that also contains an elastomer and a local anesthetic in its base form.

The presently claimed invention requires a non-aqueous environment that excludes water-absorbing agents. Therefore the compositions of Kubo are different from the compositions of the present claims. Applicants submit that the combination of Kubo with either or both of JP 10-147521 or JP 07-126157 to render the claimed invention obvious is not sustainable and should be withdrawn. Applicants respectfully request the withdrawal of the rejections.

Applicants submit concurrently herewith a certified copy of the priority document in this case. Applicants note that the Office has not properly acknowledged priority under 35 U.S.C. § 119 in this case. In the Office Action of July 2, 2002 it is noted that acknowledgement is made of the claim to priority however the basis for the acknowledgement is not noted. Applicants respectfully request the Examiner acknowledge priority under 35 U.S.C. § 119 in the next communication from the Office.

Applicants submit the amendment to the claims places all now-pending claims in condition for allowance. Applicants respectfully request the withdrawal of the rejections and the passage of all now-pending claims to Issue.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

Stefan U. Koschmieder
Registration No. 50,238

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)
NFO:SUK/bu